REMARKS

I. Disposition of the Claims

Claims 1-5 and 63-68 are pending. Claims 1-3, 5, and 63-68 stand rejected. Claim 4 is objected to. Claims 67-68 have been withdrawn but should be rejoined when claim 1 is allowable. Claim 65 has been amended.

The PTO is thanked for indicating allowable subject matter. Office action, p. 14.

II. Enablement Rejection

Claim 5 stands rejected, because the specification allegedly fails to enable the invention. Office action, pp. 3-7. Specifically, according to the PTO, the specification fails to enable "active truncated derivatives," because "Applicant has failed to define the expression 'active truncated derivatives thereof.'" Id., pp. 6-7. The rejection is improper and should be withdrawn, as there is absolutely no requirement that any applicant define any term whatsoever. MPEP § 2112. In other words, even if a term is undefined, that alone cannot make a claim nonenabled.

In fact, claims are assumed enabled. MPEP § 2164.04. When challenging a claim's enablement, the PTO must not only explain why it doubts the claim's presumptively enabling disclosure but also cite supporting evidence for its assertion. Id.

The PTO's explanation must further include specific technical reasons that cast doubt on the claim's enablement. Id. Yet, in the present rejection, the PTO's explanation consists of generalized, i.e., nonspecific, findings. For example, the PTO urged that determining "pharmacological activities" in the "pharmaceutical arts" involves screening and "[t]here is no absolute predictability even in view of the seemingly high level of skill in the art." Office action, pp. 4-5. Even if, without admission, each statement were true, it would not be

specific to "active truncated derivatives." Therefore, each of these statements is irrelevant to whether the present specification enables "active truncated derivatives."

Furthermore, not only is there no explanation casting doubt on the claim's enablement, but there is also no evidence supporting the PTO's finding. To the contrary, one, two, three, four, five, six, seven patents of record contradict the PTO's position and point to only one reasonable conclusion: ascertaining the meaning of "active truncated derivatives thereof" was within the level of ordinary skill in the art one of ordinary skill in the art when the present specification was filed. Amendment of 2/4/3. And when this evidence (the seven patents of record) is weighed against the PTO's evidence (none), the evidence and explanation show that claim 5 is enabled by the present specification. Thus, the rejection is improper and should be withdrawn.

III. Indefiniteness Rejection

Claim 5 has been rejected as indefinite. Office action, pp. 6-7. The PTO urged that the term "active truncated derivatives thereof" is "unclear" and effectively created a requirement for defining this term in the specification as-filed. Id., pp. 7 ("The specification should disclose every aspect of Applicant's invention. The specification fails to define the expression...."). But even if, without admission, the term were unclear, that finding would be insufficient to render the claim indefinite. Indeed, a claim is not indefinite merely because it poses an unclear issue of claim construction. Exxon Research and Engineering Co. v. United States, 265 F.3d 1371, 1375, 60 USPQ2d 1272, 1276 (Fed. Cir. 2001).

A claim is sufficiently definite to satisfy the statutory requirement of section 112, paragraph 2, if one of ordinary skill in the art would understand the bounds of the claim when read in light of the specification. Miles Labs., Inc. v. Shandon, Inc., 997 F.2d 870, 875, 27 USPQ2d 1123, 1126 (Fed. Cir. 1993). Most importantly here, a claim is definite if it is

amenable to construction, however unclear that task may be. Exxon, 265 F.3d at 1375, 60 USPQ2d at 1276. In other words, if the meaning of the claim is discernible, the claim avoids a rejection on indefiniteness grounds. Id.

In this rejection, the cited term is amenable to claim construction, as evidenced by the seven patents cited of record. Thus, the rejection should be reversed.

IV. Anticipation Rejections

There are three anticipation rejections, each addressed under a separate heading.

A. GB 1,503,244

Claims 3 and 65 have been rejected as anticipated by example 1(A) of GB 1,503,244. Office action, p. 9. A claim may be anticipated by a reference only if that reference describes it. MPEP § 2131. The term "described," as used in 35 USC § 102, has a particular meaning. In fact, describing requires much more than finding each and every element in a prior art reference: "The identical invention must be shown in as complete detail as is contained in the . . . claim." MPEP § 2131 (quoting *Richardson* v. *Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)). In other words, the reference must direct those skilled in the art to the presently claimed invention without any need for picking, choosing, and combining various disclosures in the reference not directly related to each other by the teachings of the cited reference. In re Arkley, 172 USPQ 524 (CCPA 1972); MPEP § 706.02(a) ("For anticipation under 35 U.S.C. 102, the reference must teach every aspect of the claimed invention either explicitly or impliedly.").

In the present case, the PTO cannot rely on GB 1,503,244 to meet this standard. GB 1,503,244 describes a fungicide or herbicide compound of Example 8, but never describes a "pharmaceutically acceptable carrier" in Example 8, and Example 8 thus never anticipates any composition comprising a "pharmaceutically acceptable carrier." Indeed, the PTO cites an unrelated passage (p. 17, ll. 39-44) and states several "carriers ... that are known ... as 'pharmaceutically acceptable carriers.'" Office action, p. 9. But, as mentioned above, citing additional passages and picking particular compounds off a list demonstrates a need for picking, choosing, and combining various disclosures of GB 1,503,244 to reach the proposed composition, which GB 1,503,244 itself never describes. Thus, the rejection is improper and should be withdrawn.

And even if GB 1,503,244 may add its compounds to a carrier to form compositions, why would GB 1,503,244's carriers be "pharmaceutically acceptable"? Clearly, the carriers may even contain insecticide, nematocide, fertilizer, synergetic agents, another herbicide, or fungicide or plant growth regulators. GB 1,503,244, p. 17, ll. 36-38. Thus, a mere list of carriers for fungicides and herbicides in GB 1,503,244 is not an inherent description of a "pharmaceutically acceptable carrier."

The PTO, nevertheless, should not ignore any claim limitations, including "pharmaceutically acceptable carrier," which GB 1,503,244 never describes in a composition comprising the cited compound. Thus, GB 1,503,244 never anticipates the composition of claim 3 or 65, and the rejection should be withdrawn.

B. WO 96/06846 (Lopez-Rodriguez)

Claims 65-66 stand rejected as anticipated by compound 1g of WO 96/06846. Office action, p. 8. WO 96/06846 (translation), however, describes arylpiperazines, which contain a piperazine unit.

A piperazinyl group contains two nitrogen atoms. On the other hand, claim 65 reads, in relevant part under R's definition, "wherein when R is an alicyclic monocyclic heterocyclic ring containing a nitrogen heteroatom, the alicyclic monocyclic heterocyclic ring contains only one nitrogen heteroatom." As a result, R differs from a piperazinyl group. Moreover, claim 66 depends from 65. Thus, WO 96/06846 (translation) neither describes nor anticipates either claim 65 or 66, and the rejection should be withdrawn.

C. Lopez-Rodriguez (J. Med. Chem (1997) 30:1648-56)

Claims 65-66 have been rejected as anticipated by compound 1a of Lopez-Rodriguez. Office action, pp. 8-9 Lopez-Rodriguez describes arylpiperazines, which contain a piperazine unit containing two nitrogen atoms. On the other hand, for the reasons just noted, claim 65's R differs from a piperazinyl group. Thus, Lopez-Rodriguez neither describes nor anticipates claim 65 or its dependent claim 66, and the rejection should be withdrawn.

V. Obviousness Rejections

Claims 1-3 and 63-66 stand rejected as allegedly prima facie obvious over the teachings of Wakabayashi (JP 52-083686), GB 1,503,244, Jamieson, and WO 96/06846, each

taken alone or in combination with each other when similar utilities are asserted. Office action, pp. 10-et seq. This rejection is improper and should be withdrawn.

A prima facie case cannot be established unless the prior art provides motivation, i.e., a desirable reason, for making the claimed invention. MPEP § 2143.01. Nor can it be established unless the prior art provides a reasonable expectation of success. MPEP § 2143.02. Yet a prima facie case has not been established here for the evidence and explanation lack the required motivation and expectation of success.

According to the PTO, the required motivation is that "indiscriminate selection of 'some' among 'many' is prima facie obvious." Office action, p. 11. This quote is based on dictum from In re Lemin, 141 USPQ 814 (CCPA 1964), a case enclosed for consideration with the last reply, a case never addressed in the most recent rejection. Consideration of those arguments from the last reply is respectfully requested. Additionally, in view of those arguments, the rejection over Wakabayashi, Jamieson, and WO 96/06846 should be withdrawn, as "it is essential that Office personnel find some motivation or suggestion to make the claimed invention" in order to establish a prima facie case, MPEP § 2144.08 II A, but the record and explanation lack the required motivation.

Nor does the explanation and evidence of record contain the required reasonable expectation of success for modifying GB 1,503,244. Even if GB 1,503,244 were to teach an isomer of any claimed invention, that alone would not be enough to render that claim prima facie obvious. "Isomers having the same empirical formula but different structures are not necessarily considered equivalent by chemists skilled in the art and therefore are not necessarily suggestive of each other." MPEP § 2144.09. In other words, isomerism by itself cannot establish a prima facie case of obviousness. Ex parte Mowry, 91 USPQ 219, 221 (Bd. Pat. App. 1950). The Federal Circuit has required, in the area of chemical structural prima

facie obviousness, that the prior art suggest the required motivation and expectation of success for achieving that motivation to support a proposed structural change. In re Grabiak, 226 USPQ 870, 872 (Fed. Cir. 1985). Since the evidence or explanation of record lacks the required reasonable expectation of success, the rejection is improper and therefore should be withdrawn.

Finally, the combination of teachings is improper. Combining references requires the desirability of the combination. MPEP § 2143.01. But the teachings of Wakabayashi, GB 1,503,244, Jamieson, and WO 96/06846 are disparate. Wakabayashi concerns germicides (p. 1); GB 1,503,244 concerns compounds for fungicidal and herbicidal activity (p. 1); Jamieson concerns compounds for treating asthma (col. 1); and WO 96/06846 concerns 5-HT_{1A} ligands (p. 2 translation). There is no reason of record to combine them. Thus, the rejection over the combination is improper and should be withdrawn.

CONCLUSION

Applicant respectfully requests that this Amendment under 37 C.F.R. § 1.116 be entered by the Examiner, placing each claim in condition for allowance. Applicant submits that the proposed amendments of the present claims do not raise new issues or necessitate the undertaking of any additional search of the art by the Examiner, since all of the elements and their relationships claimed were either earlier claimed or inherent in the claims as examined. Therefore, this Amendment should allow for immediate action by the Examiner.

Furthermore, it is respectfully submitted that the entering of the Amendment would allow the Applicant to reply to the final rejections and place the application in condition for allowance. Finally, Applicant submits that the entry of the amendment would place the

application in better form for appeal, should the Examiner dispute the patentability of the pending claims.

Applicant submits that this claimed invention, as amended, is neither anticipated nor rendered obvious in view of the references cited against this application. Applicant therefore requests the entry of this Amendment, the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims. The Examiner is invited to contact the undersigned attorney by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

Date 7/25/3

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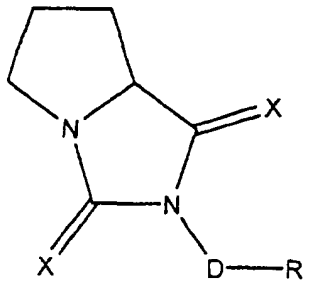
ENCLOSURE: VERSION WITH MARKINGS TO SHOW CHANGES MADE

Should additional fees be necessary in connection with the filing of this paper, or if a petition for extension of time is required for timely acceptance of same, the Commissioner is hereby authorized to charge Deposit Account No. 19-0741 for any such fees; and applicant(s) hereby petition for any needed extension of time.

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

65. (Amended) A pharmaceutical composition comprising an effective amount of a compound and a pharmaceutically acceptable carrier, wherein the compound is of the formula:



where

each X independently is O, S, or NR_2;

R_2 is selected from the group consisting of cyano, nitro, hydrogen, C_1-C_4 alkyl, hydroxy, and C_1-C_4 alkoxy;

D is a direct bond or C_1-C_8 alkyl or alkenyl;

R is hydrogen, or an alicyclic or aromatic, mono-, bi- or tricyclic, carbo- or heterocyclic ring**, wherein when R is an alicyclic monocyclic heterocyclic ring containing a nitrogen heteroatom, the alicyclic monocyclic heterocyclic ring contains only one nitrogen heteroatom**;

wherein R is optionally substituted with one substituent selected from the group consisting of hydrogen, halo, hydroxyl, nitro, trifluoromethyl, C_1-C_6 straight or branched chain alkyl, C_2-C_6 straight or branched chain alkenyl, C_1-C_4 alkoxy, C_2-C_4 alkenyloxy, phenyl, phenoxy, benzyloxy, and amino;

wherein when both X substituents are O and D is a bond, R is not phenyl;

wherein when one X is O and the other is S and D is a bond, then R is not phenyl;

wherein when both X substituents are O and R is H, D is not C_1-C_8 alkyl;

or a pharmaceutically acceptable salt, ester, or solvate thereof.